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TITLE: Computerized Tailored Intervention for Behavioral Sequelae of Post-Traumatic Stress Disorder in Veterans

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14. ABSTRACT

This project assesses the usability and feasibility of a multi-behavioral computerized tailored intervention (CTI) or expert system delivered via the Internet for veterans with Post-Traumatic Stress symptoms. Three behavioral health risk factors, (1) smoking, (2) depression, and (3) stress, that are associated with PTSD, will be included in the CTI system. The project will adapt and modify a CTI system based on the Transtheoretical Model of Behavior Change (TTM) that has been successfully utilized with general adult populations to be relevant to a veteran population. The study will utilize methods that are characteristic of a product development project. Each of the four project phases are sequential and will build upon the results of the previous phase. Phase 1 focuses on the review of current CTI programs on smoking cessation, stress management, and depression prevention, and integrating them into a multi-behavioral program for application with veterans. Phase 2 will include the development and adaptation of text-based feedback messages and multimedia components for smoking cessation, stress management, and depression prevention. Initial testing of the modified CTI programs will commence in Phase 3. Cognitive and usability testing with veterans will be performed, and additional modifications to the behavioral modules will be made based on the test results. Phase 4 will focus on feasibility testing of the multi-behavioral CTI system with veterans.

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INTRODUCTION

The overall aim of this project is to enhance the emotional and physical well-being of veterans with Post-Traumatic Stress symptoms through the reduction of smoking, depression, and stress with the use of an empirically based computerized tailored intervention (CTI) or expert systems. The more immediate objective of the project is to adapt and modify a successful CTI system for the general adult population to be relevant and applicable to military veterans with Post-Traumatic Stress symptoms, particularly those who have been deployed to Iraq and Afghanistan. Research with returning Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) veterans suggests that there is a new generation of veterans with high levels of Post-traumatic Stress Disorder (PTSD) and depression (Hoge et al., 2006). Therefore, it is critical that we identify effective ways to increase access to efficacious treatments for combat-related PTSD and associated co-morbid behavioral health conditions. Further, due to the rapid development of telemental health programs throughout the military, it is crucial that research address the effectiveness of this mode of service delivery for specialty services such as PTSD treatment.

This proof of concept project will develop and pilot test a viable Internet-based intervention to assist veterans with Post-Traumatic Stress symptoms to progress toward changing negative health behaviors that are associated with PTSD and are often difficult to change. Most commercially available CTIs and software applications have limited impact, because of the lack of theory-driven material and empiricism. The proposed CTI is supported by more than 30 years of scientific evidence, and uses the Transtheoretical Model of Behavior Change (TTM) as the theoretical basis for generating personalized interventions (Prochaska & Velicer, 1997; Velicer, Prochaska, & Redding, 2006). The TTM is ideally suited to those who are resistant to change and unlikely to take action in the near future, as well as those prone to relapse.

The intervention will be primarily targeted at negative coping strategies that confound or exacerbate Post-Traumatic Stress symptoms and hinder progress toward remission. Progress in a TTM conceptual framework may be defined as movement from one TTM stage of change to the next level of the change process, rather than the elimination or significant reduction of smoking, depression, or stress per se. The CTI system that will be modified during this project has been empirically tested and validated with a general population and has demonstrated significant outcomes for the three proposed modules — smoking cessation, depression prevention, and stress management. The proposed CTI system will provide an intervention that emphasizes advancement through the processes of change at one's own pace as the focus of project, rather than the linear progression through a structured behavior change program to achieve changes in the undesired behaviors.

Hypothesis 1: *The structure and TTM-based content of the adapted Smoking Cessation, Depression Prevention, and Stress Management systems and consequent CTI will be appropriate for veterans.*

> **Primary Aim 1:** To modify TTM-based Smoking Cessation, Depression Prevention, and Stress Management behavioral intervention modules, originally developed for

general adult populations, to be appropriate and relevant for veterans with Post-Traumatic Stress symptoms.

Secondary Aim 1a: To conceptualize the CTI program's approach, content, and design based on input from a diverse sample of military veterans and expert consultants.

Hypothesis 2: *A multi-behavioral CTI can be successfully implemented with veterans who have Post-Traumatic Stress symptoms*

Primary Aim 2: To demonstrate that a multi-behavioral CTI can be successfully implemented with veterans with Post-Traumatic Stress symptoms.

Secondary Aim 2a: To conduct usability interviews with veterans to ensure that the target population can navigate through the computerized intervention and understand the intervention content.

Secondary Aim 2b: To demonstrate the feasibility of CTI by: a) recruiting veterans to the project and delivery of the proposed intervention; and b) assessing the acceptability and perceived usefulness of the intervention from the perspective of veterans with Post-Traumatic Stress symptoms.

Secondary Aim 2c: To demonstrate feasibility of CTI to increase motivation to change targeted behaviors, i.e., smoking cessation, depression prevention, and stress management.

Secondary Aim 2d: To demonstrate positive change in assessment outcomes for Post-Traumatic Stress symptoms, depression, quality of life, and perceived stress.

BODY

During the first year of the project, personnel changes and VA requirements resulted in a 14-month delay in the actual start of the 18-month project. Fortunately, progress in the second year has been good and the first 3 phases of the research have been completed. A summary timeline is presented below.

Year One

1. August 12, 2009: Project awarded.
2. November 19, 2009: Revised protocol approved by the VA IRB.
3. January 19, 2010: UH IRB approval notification.
4. February 9, 2010: Protocol packet prepared for second level review, and submitted to MRMC ORP Human Research Protections Office (HRPO) through TATRC.
5. March 8, 2010: Human Use approvals received from HRPO for both UH and VA protocols.
6. July 27, 2010: Transition of PI from Dr. Sarah Miyahira to Dr. James L. Spira, Ph.D. approved by funding agency.

Year Two

1. September 15, 2010: Approval of IRB amendments to change the PI name and affiliation on protocol, consent form, waiver of HIPAA authorization, and all other project documents approved.
2. Sept. 17, 2010: Budget Modification approved.
3. October 5, 2010: Research Project Manager hired and commenced work.
4. October 20, 2010: Subaward agreements executed with the University of Hawaii and Pro-Change Behavior Systems, Inc., and two consulting contracts.
5. October 14, 2010: Continuing Review approved by VA IRB.
6. October 22-23, 2010: Kick-off Meetings held at VAPIHCS.
7. November 22, 2010: HRPO approved Continuing Review.
8. November 2010: All technical and financial reports brought up to date for the award and subawards as soon as research project manager learned that previous reports had not been submitted.
9. January 13, 2011: IRB Amendment to clarify ambiguities in the protocol; request a waiver of informed consent documentation and a waiver of HIPAA Authorization approved for Phases 1 & 3 by VA IRB and ISO/PO.
10. January 18, 2011: CRADA finalized with Pro-Change.
11. January-March, 2011: Phase 1 Focus Groups, data transcription, and analysis completed.
12. March 1, 2011: Eleven-month no cost extension received with a new POP end date of February 2, 2012.
13. April 2011: Phase 2 system modification and adaption based on focus group findings completed.
14. April 14, 2011: Amendment to request a waiver of documentation of informed consent and a waiver of HIPAA Authorization for Phase 4 to allow online screening and consenting due to minimal risk of interacting with an expert system; replace two approved measures; and related updates to study protocol approved by the VA IRB and ISO/PO.
15. May-June, 2011: Beta testing and Usability testing and synthesis completed.
16. May 23, 2011: IRB approved use of Vet Center in Honolulu as external site for usability testing.
17. June 21, 2011: IRB approved changes to the protocol, online assessments and measures per usability testing findings.
18. July 14, 2011: Waivers of authorization and informed consent for recruitment purposes were approved at the IRB board meeting.
19. July 19, 2011: Revised feasibility recruitment flyer and invitation letter approved.
20. July 22, 2011: STR2IVE Program launched and 800 invitations mailed to OEF/OIF veterans with PTSD diagnosis.
21. August 2, 2011: IRB approved expansion of inclusion criteria for PCL-M measure.
22. August 5, 2011: Submitted request for expansion of inclusion criteria for PHQ-8 measure.

Progress this Period (See Gantt chart in Appendix A):

Task 1: IRB Protocol review and approval – 100% complete

1a. Local IRB – approved, continuing review approved – 100% Complete

1b. 2nd level-USAMRMC -approved – 100% complete

- IRB Amendment to revise smoking focus group flyer approved December 1, 2010
- Received approval January 13, 2011 for waiver of documentation of consent and waiver of HIPAA authorization for Phases 1 and 3 of study; revised protocol; and prescreening questions.
- IRB Amendment approved January 25, 2011 to revise stress and depression focus group flyer.
- On April 14, 2011, the VA IRB and ISO/PO approved a waiver of documentation of informed consent and a waiver of HIPAA Authorization for Phase 4 to allow for online screening and consenting due to minimal risk of interacting with expert system; replace two approved measures; and related updates to study protocol.
- Received approval May 12, 2011 for a waiver of the requirement to maintain a master list since we have a waiver of documentation of informed consent.
- Received approval May 24, 2011 for use of Veterans Center as external site for usability testing and other project activities.
- Received approval June 21, 2011 for an IRB amendment for revisions to questionnaires based on beta and usability testing results.
- Received full IRB board approval for a waiver of authorization and a waiver of informed consent for recruitment purposes July 14, 2011 which allowed us to access VA PIHCS records to do a targeted recruitment mailing for the Phase 4 feasibility study.
- Received IRB approval of revised flyers and recruitment letter for Phase 4 mailing on July 19, 2011.
- Submitted documentation for continuing review to VA IRB on August 4, 2011.
- Submitted amendments to widen the inclusion range to improve recruitment efforts and screen-in rate for the feasibility study in early August 2011 due to new information and an unacceptably high rate of recruits being screened out.

Task 2: Project planning and coordination – in progress (75% complete)

- Completed Kick-off meetings with VAPIHCS, Pro-Change, and Univ. of Hawaii team members on October 21-22, 2010. (See Q5 Report for agenda and slides from joint meeting for details.)
- Setting up research clinics to meet VA requirement to add progress note and consent form to the CRPS database.
- Completed IRB training on VA consenting requirements and CPRS training.
- Coordinating with PRRP ward to use rooms for focus groups with ACC rooms as back-up to allow for after hours focus group meetings.
- Received research clinic code on November 24, 2010 to meet VA requirement to add progress note and consent form to the CRPS database.
- Completed IRB monitoring of consenting process for focus groups.
- Received approval of CPRS progress note for CTI project.
- Scheduled PRRP room for use for focus groups and purchased necessary supplies.
- CRADA between subcontractor and VAPIHCS was completed and signed.
- Met with Mental Health in ACC to receive permission to use Tech Lab for usability interviews
- Met with Veteran Student association at UH for recruitment.
- Planning recruitment for usability and feasibility participants. Planning recruitment for usability and feasibility participants.
- Finalized recruitment advertising for usability testing.
- Procured supplies and software for usability assessment and analysis.

- Met with Vet Center and IRB to discuss conducting some usability interviews at the Vet Center to recruit more OEF/OIF Veterans.
- Recruited and scheduled all usability testing sessions.
- Coordinated the use of the Vet Center in addition to VAPIHCS for conducting usability interviews in order to include more OEF/OIF Veterans.
- Purchased and implemented first batch of electronic gift cards incentives for Phase 4 feasibility study.
- Planned and coordinated data pull and mailing for initial feasibility recruitment.
- Coordinated finalization of CTI system, process flow, helpdesk, and assessment timing.
- Planning second phase of feasibility recruitment.
- Planning second batch purchase and implementation of gift card incentives for Phase 4 feasibility study incentives.
- Planning additional mailings, advertising, and other recruitment for Phase 4 after expanded inclusion criteria is approved and implemented.

Task 3: Focus groups for 3 modules – 100% complete

3a. Recruit Veterans – 100% complete

3b. Conduct focus groups – 100% complete

- Practice focus group session held December 1, 2010.
- Room location and dates finalized.

3c. Analyze data & identify content changes –100% complete

- Recruitment plan being drafted.
- Recruitment for focus groups was done primarily at the VA and some areas of Tripler.
- Focus groups were held at PRRP at Tripler on the evenings of December 14, 2010, January 28, 2011, and February 4, 2011.
- All focus group recordings were confirmed to meet VA requirements for de-identified data.
- Questionnaire data entered in spreadsheet for reference on the staging and demographic composition of the groups.
- Smoking focus group transcription, analysis and report completed.
- Stress focus group transcription, analysis and report completed.
- Depression focus group transcription, analysis and report completed.
- Completed additional report summarizing all three focus group findings.

Task 4: Integrate modules into multi-behavioral CTI with single home page –100% complete

- Pro-Change completed development work on the integration of modules.

Task 5: Modify & tailor 3 modules to Veterans – 100% complete

5a. Modify content of feedback narratives for each module – 100% complete

- Researched best adaptation for OEF/OIF Veterans
- Pro-Change adapted modules for OEF/OIF Veterans based on findings.
- Modifications completed based on reports from the focus groups and other research.

5b. Modify CTI program –100% complete

- After receiving smoking, stress, and depression module adaptation reports from the focus groups, Pro-Change has completed development work to modify screens for the smoking and stress modules, and is 85% complete with the depression module.

Task 6: Conduct beta test & usability interviews–100% complete

6a. Beta test CTI system – 100% complete

- Two rounds of internal beta-testing completed for smoking module in April 2011.
- First round of beta-testing for stress and depression modules completed in early May
- Second round beta-testing of multi-behavioral system began in early May.

6b. Recruit Veterans & conduct usability interviews – 100% complete

- Revised protocol to allow for online recruitment through Veteran organizations and the VA
- Procured, installed, and tested usability testing software to improve quality of the usability testing analysis and reports.
- Recruited participants for usability interviews.
- Completed all first and second round usability test sessions.
- Recorded results of usability testing and made recommendations for adapting the system to meet the needs of the Veteran users.

6c. Modify CTI program- 100% complete

- Revisions to smoking module interface and content in progress based on focus group reports and beta-testing (over 100 image, grammar, semantic and usability issues and bugs have been logged and are currently being addressed)
- Stress and depression module modifications to be completed in May and June.
- Revisions based on usability reports completed for interface and system content.
- Smoking, stress, and depression module final modifications that could be completed by the July 21 launch have been completed.
- Resolved all issues reported in FogBugz collaborative development and bug tracking system. Given the reduced time to complete the study, some improvements could not be completed within the allowed timeframe.
- Completed additional improvements to the online workbook that were discovered during usability testing.
- Implemented the use of an access code to deter one participant from creating multiple accounts.
- Administrative monitoring page completed for Hawaii team to track recruitment and enrollment in feasibility study.
- STR2IVE Program officially launched on July 21, 2011.

Task 7: Conduct feasibility study– (15% complete)

7a. Recruit veterans & orient to CTI system – (35% complete)

- Mailed invitations, flyers, and study fact sheets to a targeted list of 800 Veterans in the Pacific Island Health Care System catchment area on July 22, 2011.
- As of August 9, 2011, 60 individuals have registered on the site, but only nine have met the inclusion criteria for the study and could enroll in the study.

7b. Conduct baseline and post assessments – (5% complete)

- Nine enrolled participants have completed the baseline measurements, and six have completed 2 programs per study requirements to receive the first incentive gift card code.

7c. Analyze data & interpret results – (0% complete)

Task 8: Submit final report– (0% complete)

8a. Prepare & submit final report– (0% complete)

8b. Initiate manuscript preparation– (10% complete)

- The first manuscript on the study concept accepted for publication, upon completion of minor revisions, to *Translational Behavioral Medicine: Practice, Policy and Research*.

8c. Prepare presentation for scientific meeting– (0% complete)

KEY RESEARCH ACCOMPLISHMENTS

1. Accomplished all required due diligence and administrative work to receive a highly unusual VA IRB approval to waive consent forms and HIPAA authorization for all phases of this study. This approval was sought to allow veterans to consent, screen, and enroll, and test the new program anonymously from the privacy of their own homes, without having to provide social security numbers or have their medical records accessed in order to add required progress notes regarding their participation in the study.
2. Completed all aspects of Phases 1-3 of the study according to the revised shortened timeline submitted for the no cost extension.
3. Launched the revised STR2IVE Program on July 22, 2011 and began recruiting the target population through the VAPIHCS database the following day.
4. STR2IVE Program is functioning as planned and participants are gradually enrolling in the study.
5. Manuscript on the study concept entitled "A Computerized, Tailored Intervention to Address Behaviors Associated with PTSD in Veterans: Rationale and Design of STR2IVE" has been accepted for publication in *Translational Behavioral Medicine: Practice, Policy and Research.*

REPORTABLE OUTCOMES

1. All protocol elements (e.g., study design, informed consent, recruitment materials, etc.) have been approved by the local VA and USAMRMC (ORP).
2. The study's public name is "Stress Reduction Strategies to Improve Veterans' Health.

3. Manuscript has been accepted pending revisions on the study concept entitled "A Computerized, Tailored Intervention to Address Behaviors Associated with PTSD in Veterans: Rationale and Design of STR2IVE" has been accepted for publication in *Translational Behavioral Medicine: Practice, Policy and Research.*

CONCLUSION

Significant advances in the study timeline have been made over the past year. The original 18-month timeline was reduced to 14 months, and substantial efforts have been made to launch the program despite numerous content and design revisions to the system. Personnel changes compounded the delays caused by IRB and VA requirements during the first year of the project, but clear progress is evident in year two. Three of the four phases have been successfully completed. The PI change and efforts to protect the anonymity of veteran participants precipitated further amendments to the protocol and research documents. A new research project manager commenced work in October 2010 and during that month the subaward agreements with the University of Hawaii and Pro-Change Behavior Systems, Inc., and two consulting contracts were executed. Kick-off meetings with VAPIHCS, Pro-Change, and University of Hawaii team members were held at

VAPIHCS on October 21-22, 2010. All technical and financial reports were brought up to date for the award and subawards as soon as the new research project manager was made aware that previous reports were missing. The VA changed a previous decision and later required a CRADA to be drafted for one subaward, and this CRADA was finalized on January 18, 2011.

The Phase 1 focus group recruitment, data collection and analysis began in December 2010 and were completed in March 2011. An 11-month no-cost extension was awarded March 1, 2011 with a new POP end date of February 2, 2012. The Phase 2 and 3 system development and adaption, beta-testing, and two rounds of usability testing and development were completed April -July 2011. Changes to the protocol, online assessments and measures per usability testing findings were all approved by the VA IRB during this time to allow for online consenting, screening, and enrollment in the study. New recruitment materials, waivers of authorization and informed consent for recruitment purposes were also approved by IRB to allow targeted mailings to veterans with PTSD.

The final STR2IVE system was launched for the Phase 4 feasibility study on July 22, 2011. Given the delay in start-up and the challenges of recruiting veterans with mild to moderate PTSD who qualify for the study, a three-month no-cost extension will be required in order to collect enough data for the Phase 4 longitudinal feasibility study prior to the end of the POP. Sufficient funds remain in the budget to allow for this additional time to recruit and collect data.

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APPENDIX (Revised Timeline)

ID	Task Name	Duration	Start	Finish
1	Project Duration	347 days?	Thu 10/14/10	Fri 2/10/12
2	**Reports**	**351 days?**	**Fri 11/5/10**	**Fri 3/9/12**
15	**IRB protocols (site 1 & 2)**	**140 days?**	**Mon 10/4/10**	**Fri 4/15/11**
16	prepare protocol for submission to local IRB	1 day	Mon 10/4/10	Mon 10/4/10
17	Local IRB review and approval	1 day	Mon 10/4/10	Mon 10/4/10
18	2nd level review and approval	1 day	Mon 10/4/10	Mon 10/4/10
19	Amendments - Phases 1 & 3	33 days?	Wed 12/1/10	Fri 1/14/11
20	Amendments - Phase 4	46 days	Fri 2/11/11	Fri 4/15/11
21	Project planning & coordination of multi-team sites	306 days	Wed 10/20/10	Wed 12/21/11
22	**Conduct focus groups (sites 1 & 2)**	**103 days**	**Wed 10/27/10**	**Fri 3/18/11**
23	Recruit Veterans (n=30)	57 days	Wed 10/27/10	Thu 1/13/11
24	Conduct focus groups	21 days	Fri 1/14/11	Fri 2/11/11
25	Analyze data & identify content modifications	45 days	Mon 1/17/11	Fri 3/18/11
26	**Integrate 3 Modules into single multi-behavioral CTI homepage**	**90 days**	**Mon 1/31/11**	**Fri 6/3/11**
27	**Modify modules (language, tone, & content-all sites)**	**90 days**	**Mon 1/31/11**	**Fri 6/3/11**
28	smoking cessation	36 days	Mon 1/31/11	Mon 3/21/11
29	stress management	30 days	Mon 2/28/11	Fri 4/8/11
30	depression prevention	30 days	Mon 3/28/11	Fri 5/6/11
31	Testing and system integration	20 days	Mon 5/9/11	Fri 6/3/11
32	**Conduct CTI system beta & usability testing (sites 1 & 3)**	**89 days**	**Mon 3/21/11**	**Thu 7/21/11**
33	Recruit Veterans (n=15)	23 days	Mon 3/21/11	Wed 4/20/11
34	Conduct system beta testing	21 days	Mon 4/11/11	Mon 5/9/11
35	conduct usability interviews with veterans (n=15)	15 days	Tue 5/10/11	Mon 5/30/11
36	Modify system based on interview data as needed	38 days	Tue 5/31/11	Thu 7/21/11
37	**Conduct feasibility study (site 1)**	**118 days**	**Mon 7/4/11**	**Wed 12/14/11**
38	Recruit participants and orient to CTI system (n=50)	40 days	Mon 7/4/11	Fri 8/26/11
39	Conduct 1 month online assessment	40 days	Thu 8/18/11	Wed 10/12/11
40	Conduct 3 month post assessment	40 days	Thu 10/20/11	Wed 12/14/11
41	Analyze & interpret data (site 1, 2 &3)	16 days	Thu 12/15/11	Thu 1/5/12
42	**Submit final reports and publications**	**80 days**	**Fri 1/6/12**	**Thu 4/26/12**
43	prepare and submit final report	20 days	Fri 1/6/12	Thu 2/2/12
44	prepare manuscript for publication	30 days	Fri 2/3/12	Thu 3/15/12
45	prepare for scientific meeting	30 days	Fri 3/16/12	Thu 4/26/12